

**REMARKS**

The present paper is presented in response to the office action dated June 19, 2009. This paper is being filed with a petition and fee for a one-month extension of time to respond and as such, the response is timely filed on October 19, 2009. The response is accompanied by a request for continued examination

**A. Status of the Claims**

Claims 21, 22, 24-26, 28, 30 and 32-37 were pending in the instant application. Claims 21, 22 and 24-26, 28, 30 and 32-37 were rejected under 35 U.S.C. 112 first paragraph for allegedly lacking written description. Claims 32 was rejected under 35 U.S.C. 102(a) and 102(e) as allegedly anticipated by Calvert 6,500,662. Claims 25 and 30 were rejected based on the disclosure of WO 92/21375 and claims 21, 22 and 23-31 were rejected under 35 U.S.C. 103 over a combination of WO 92/21375 and Moorman et al (J. Virology, vol 70, pages 763-770).

Claims 21, 22, 25, 26, 28 and 32, have been amended to specifically recite that the infectious clone is of virus strain deposited under accession number CNCM I-1102.

**B. Rejection under 35 U.S.C. 112, first paragraph and second paragraph**

Claims 21, 22 and 24-26, 28, 30 and 32-37 were rejected under 35 U.S.C. 112 first paragraph as allegedly failing to comply with the written description requirement. According to the examiner, while SEQ ID NO:18 is described "Applicant has not taught where to find additional members of the genus and applicant has not shown possession of sufficient members of the genus to have possession of the claimed genus." Further the examiner

rejected these claims for lack of enablement for reciting clones in the prior art that do not contain SEQ ID NO:18 at the 5' end. Finally, the Examiner noted that while CNCM I-1102 contains SEQ ID NO:18 at the 5'end in other viruses the 5' end is not SEQ ID NO:18.

Each of the above rejections under 35 U.S.C. 112 is believed to be addressed by the amendment to claims 21, 22, 25, 26, 28 and 32 presented above. The amendment limits the virus strain from which the infectious cDNA clone is prepared to PRRS virus strains deposited under accession number CNCM I-1102.

Applicants believe this claim amendment overcomes the rejections based on 35 U.S.C. 112, first paragraph and also the rejection based on 35 U.S.C. 112, second paragraph.

### **C. Rejection under 35 U.S.C. 102(a) (b) and (e) in view of Calvert et al**

Claim 32 was rejected under 35 U.S.C. 102(a) and (e) as being anticipated by Calvert et al in that it purportedly read on a sequence of SEQ ID NO:1 disclosed in Calvert. Claim 32 has been amended to recite: "An isolated nucleic acid comprising a DNA sequence that encodes chimeric virus comprising a genome-length infectious RNA clone of PRRSV virus strain deposited under accession number CNCM I-1102 wherein the chimeric virus expresses the ORF 7 of PRSS strain ATCC VR2332 wherein said isolated sequence comprises a sequence of SEQ ID NO:18 at its 5' end. to refer to a chimeric." An infectious DNA clone based on the full length genome of CNCM I-1102 was not shown in Calvert. As such, Applicants submit that claim 32 as currently amended is novel in view of Calvert.

**D. Rejection under 35 U.S.C. 102(b)**

Claims 25 and 30 were rejected under 35 U.S.C. 102(b) as anticipated by WO 92/21375. Claim 30 has been cancelled. Claim 25 has been amended to specifically recite that the infectious virus clone is produced according to a specific process: ("generated by a process comprising transfecting a host cell not susceptible to infection with wild-type PRRS virus strain CNCM I-1102 with a recombinant nucleic acid comprising at least one full-length DNA copy of the genome of CNCM I-1102 wherein the recombinant nucleic acid comprises a sequence of SEQ ID NO:18 at its 5' end and isolating said infectious clone from said transfected host cell"). As noted recently by the Federal Circuit in *Abbott Laboratories v. Sandoz, Inc.*, 566 F.3d 1282, 2009 WL 1371410 (Fed. Cir. May 18, 2009), "process terms in product-by-process claims serve as limitations" (adopting the rule in Atlantic Thermoplastics, 970 F.2d at 846-47, (Fed Cir. 1991)). As such, the Applicants have added specific limitations to product claim 25 which distinguishes it from the disclosure of WO 92/21375. More particularly, at the time of publication of WO 92/21375 it was not known how to produce infectious cDNA clones of PRRS virus. The present claim amendment specifically recites that the infectious RNA molecule is prepared using an infectious full length cDNA. Applicants believe this claim amendment overcomes the rejection based on WO 92/21375. Applicants request reconsideration of the rejection in view of the amendment.

**E. Rejection under 35 U.S.C. 103(a)**

Claims 21, 22 and 23-31 were rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over WO 92/21375 in view of Moormann et al (J. of Virology, Vol 70 pp 763-770). Applicants respectfully disagree with the Examiner.

The claims as presented are directed to specific a cDNA infectious clones of PRRS virus strain deposited under accession number CNCM I-1102. As noted in the application, the use of such cDNA clones “circumvent[s] the problems encountered in viral RNA strand synthesis associated with the presence of incomplete viral RNA fragments.” [para. 0013]. The specification teaches that “the utmost 5’ end of the viral genome in genome length cDNA [creates] an infectious clone” [para. 0068] and that the presence of this 5’ cap structure allowed the inventors to overcome the problems of producing the infectious clones.

WO 92/21375 provides the basic disclosure of the nucleic acid sequence of a PRRS virus strain. However, nowhere in WO 92/21375 is there a teaching that it would be desirable to include a specific sequence of SEQ ID NO:18 at the 5’ end of the virus genome to render that genome infectious. Likewise, Moormann et al. fails to provide any guidance as to why a sequence of SEQ ID NO:18 as opposed to any other sequence would be particularly useful in rendering a PRRS virus infectious. Thus, the teachings of the prior art are inadequate for rendering specifically claimed sequences obvious.

While the prior art, including WO 92/21375, may well have identified various PRRS viruses, as specifically noted in the specification, routinely infectious clones of such viruses were not described (page 10, ¶0029). It was the teachings of the present invention that showed that incorporating a sequence of SEQ ID NO:18 into the utmost 5’ end into genome-length cDNA of those viruses to created infectious clones. With this teaching it is now possible to generate infectious clones of viruses known in the art. Such viruses can then be used as delivery vehicles for generating an immune response.

In view of the above discussion and the amendment to the claims , Applicants believe the rejection of claims 21, 22 and 24-25, 28 and 30 under 35 U.S.C. 103(a) should be withdrawn.

**F. Closing Remarks**

Applicants believe the above remarks and amendments overcome the outstanding rejections and Applicants request withdrawal of the rejections and reconsideration of the claims for allowance. No additional fees are believed to be due, however, should fees be deemed necessary or should there be an overpayment, the Commissioner is authorized to charge any additional fees or credit any overpayment to the Deposit Account of McAndrews, Held & Malloy, Account No. 13-0017.

Dated: October 15, 2009

Respectfully submitted,

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